



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,530	09/30/2003	Hans-Hinrich Sievers	NI 158	6094

7590 04/29/2005

Klaus J. Bach
4407 Twin Oaks Drive
Murrysville, PA 15668

EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/675,530	Applicant(s) SIEVERS, HANS-HINRICH	
	Examiner Suzette J Gherbi	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 8-10, 14-17 is/are rejected.
- 7) ☒ Claim(s) 2, 4-7, 11-13 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's supplementary amendment dated 2/11/05 has been received in application serial number 10/675,530.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular there is no mention in the specification for the limitations of "...toward the area of the largest flow gradient of the blood through the blood flow passage...". Applicant's specification only mentions "*...with the design of the annular body 11 as described above the artificial valve may be relatively large so that the pressure gradient in the blood flow through the valve is relatively small and there is little pressure loss generated by the valve ...*". (see pg. 14, line 20). The amended claim is different from what is actually present in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 8, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Philippe et al. 4,820,299. Philippe et al. discloses the invention as claimed noting figures 1-8 comprising: An artificial heart valve with an annular body;(2) means for mounting by surgical procedures and defining in its interior a blood flow passage (3); flap/leaflet elements (5, 6, 7) which are pivotally supported by pivot support structures; wherein the annular body includes circumferentially spaced projections (16) extending inwardly into the flow passage; wherein the projections are provided at there inwardly extending ends with pivot joints (17, 18, 19) on which the flap elements are pivotally supported. The intended use recitation/functional language *toward the area of the largest flow gradient of the blood through the blood flow passage* carries no patentable weight in the absence of any distinguishing structure. Phillips clearly discloses the structure as *claimed* and is found to be inherently capable of performing the function (see col. 11, lines 31-34 of Philips).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 8-9, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philippe et al. in view of Bokros et al. 5,843,183. Philippe et al. has been disclosed above however Philippe et al. does not disclose a recess in the valve flap/leaflet or a suture ring. Bokros et al. teaches a tri-leaflet heart valve wherein the flap/leaflet has a recess (51) and a suture ring.(35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the flap/leaflet of Philippe with a slight recess because the recess could serve as guide for surfaces and easier opening and closing of the valve and is merely a design modification. It also would have been obvious to add a sewing ring because it would further allow the surgeon to sew the device into place and is well known in the art.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philippe in view of Patke et al. Philippe has been disclosed above however Philippe does not disclose the specific material of titanium or titanium alloy. Patke et al. teaches that heart valves (including leaflets) can be made of numerous materials including titanium

Art Unit: 3738

and/or alloy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the heart valve of Philippe out of these materials because they are well known for the durability in the prosthetic art.

9.. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philippe in view of Woo et al. 6,761,736. Philippe has been disclosed but does not specify the use of coating the annular body and flap with a hard material layer. Woo et al. teaches that heart valves can be coated with a hard material layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make to coat the device of Philippe et al. with a hard coating because the coating would increase durability, provide fatigue resistance and is compatibility with the substrate and is well known in the art.

Allowable Subject Matter

8. Claims 2, 4, 5-7, 11, 12-13, 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed 2/11/05 have been fully considered but they are not persuasive. Applicant has amended claim 1 and contends that Phillips does not disclose

inwardly extending ends provided with pivot joints. Applicant also thinks that Phillips only has guide mechanisms. As stated above Phillips inwardly projecting ends are equated as the stirrups (16) and the pivot joints of Phillips are elements (17,18,19 "spurs"). The term pivot as defined by the American Heritage Dictionary is "*a short rod or shaft about which a related part rotates or swings*". Clearly elements (47-19) of Phillips meet this definition and serve as *pivot joints and the flap elements are pivotally supported* as currently claimed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3738

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

13. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J-J Gherbi', is written over a horizontal line.

Suzette J-J Gherbi
20 April 2005